

EASTMAN

**Chlormequat Chloride
(PC 18101)
June 4, 2019**

Agenda

**Preregistration Meeting between EPA and Taminco,
a subsidiary of Eastman Chemical Company
Chlormequat Chloride (PC 18101)**

June 4, 2018

2:30 pm – 3:00 pm

* Introductions:

Attendees:

Taminco/Eastman:	John Hoyt (regulatory affairs) Jessica McLaughlin (regulatory affairs) Rebecca Currie (regulatory ecotoxicologist) Len Velsor (senior counsel)
Steploe & Johnson:	Juli Mann (regulatory specialist) Sarah Beth Watson (of counsel attorney)

- * History
- * Deficiencies
- * Taminco's Next Steps
- * Anaerobic Soil Metabolism Waiver
- * Chlormequat Chloride Data Call-In

History

- December 7, 2018 – Submission of Section 3 Registration to EPA
- March 26, 2019 – Received 10 Day Deficiency Letter from EPA
- March 27, 2019 – Eastman submitted response to 10 Day Deficiency Letter
- May 8, 2019 – Received rejection letter from EPA

Noted Deficiencies

Guideline	Study
835.2410	Soil Photolysis
850.4500	Non-Vascular Aquatic Plant Toxicity - marine diatom (Skeletonema costatum)
850.4500	Non-Vascular Aquatic Plant Toxicity - freshwater diatom (Navicula pelliculosa)
850.1350	Chronic Saltwater Vertebrate
850.1400	Chronic Saltwater Invertebrate
850.6100	The associated Independent Laboratory Validation for the Environmental Chemistry Method in water

Response to Noted Deficiencies

- Taminco will initiate new studies for:
 - Soil Photolysis
 - Non-Vascular Aquatic Plant Toxicity - marine diatom (*Skeletonema costatum*)
 - Non-Vascular Aquatic Plant Toxicity - freshwater diatom (*Navicula pelliculosa*)
 - Non-Vascular Aquatic Plant Toxicity - freshwater green alga (*Raphidocelis subcapitata*)
 - Chronic Saltwater Vertebrate
 - Chronic Saltwater Invertebrate
 - Independent Laboratory Validation for the Environmental Chemistry Method in water

Next Steps

- Taminco expects all final reports to be complete by February 2020
- Taminco will resubmit a Section 3 registration for a TGA of chlormequat chloride that will be used to formulate our end-use product
- Taminco will resubmit a Section 3 registration for an End-Use Product (containing 54.87% chlormequat chloride by weight) for use as a growth regulator on wheat, barley, triticale, oats, and grasses grown for seed

Anaerobic soil metabolism study

- Taminco had a pre-submission meeting with EPA in July 2016 and discussed the requirement of the Anaerobic soil metabolism study
- In the agreed upon meeting notes EPA stated:
 - *For the Anaerobic Soil Metabolism and the Anaerobic Aquatic Metabolism studies, only one of the two is required*
 - *Taminco is required to submit a formal waiver for the study that will not be completed*
 - *Of the Anaerobic Soil Metabolism and the Anaerobic Aquatic Metabolism studies, EPA prefers to see the Anaerobic Aquatic Metabolism study*

Anaerobic soil metabolism study

- In the May 8, 2019 rejection letter EPA stated:
 - *The Agency will not formally review the waiver until a complete application is submitted. However, should you decide to submit this proposed first food use application in the future, a meeting can be scheduled with the Agency to discuss this data waiver.*

Questions

- Does EPA still agree a waiver will be acceptable for Anaerobic soil metabolism study?
- When Taminco resubmits the Section 3 registration in 2020, how can we be assured that there will be no additional deficiencies once the issues in the May 8, 2019 letter are addressed?

Chlormequat Chloride DCI

- Fine Agrochemical will be citing several of our Chlormequat Chloride Studies to satisfy the recent DCI
- EPA will be reviewing these studies prior to our Section 3 submission
- Might this have a positive impact on the timing of our Section 3 registration?